Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 8 **dated** 17/1/2023 **Regarding NCMDR FSCA of ORTHO VISION and ORTHO VISION Max Analyzers from (mfr: Ortho-Clinical Diagnostics).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 8 / 2023

24 -06-1444 H
17 -01-2023

Field Safety Corrective Action of ORTHO VISION and ORTHO VISION Max Analyzers from Ortho-Clinical Diagnostics

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18398
Product	ORTHO VISION and ORTHO VISION Max Analyzers.
Description	Blood analyzer.
Manufacturer	Ortho-Clinical Diagnostics.
Local Agent	Al Hashar Pharmacy.
The affected products	Affected Product: ORTHO VISION® Analyzer; Product Code (Unique Device Identifier): 6904579 (10758750012831) Affected Product: ORTHO VISION® Max Analyzer; Product Code (Unique Device Identifier): 6904578 (10758750012848) Software: All Software versions prior to 5.14.5 (Which is expected to be available Q1 2023 Affected Publications: Self Service Customer Procedure Guide (VISION BioVue); Publication Number: J55658 Affected Publications: Self Service Customer Procedure Guide (VISION Max BioVue); Publication Number: J55660
Reason	Potential for False Positive Results due to Carryover when Only Using the Self-Service Customer Procedures Guide for a Probe Replacement.
Action	1. Ensure the Daily Maintenance task is performed after replacing a probe offline, using only the Self-Service Customer Procedure Guide. 2. When changing the probe offline, ensure that the Pump Test and Daily Maintenance are completed. 3. The next version of the software (5.14.5) will update both the onboard and offboard publications 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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